

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UMB BANK, N.A., solely in its capacity as  
Trustee under the Contingent Value Rights  
Agreement by and between Bristol-Myers  
Squibb Company and Equiniti Trust  
Company, dated November 20, 2019,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY  
and EQUINITI TRUST COMPANY, LLC,

Defendants.

Case No. 1:24-cv-8668  
[rel. 1:21-cv-04897-JMF]

**AMENDED COMPLAINT**

**JURY TRIAL DEMANDED**

By and through its attorneys, Plaintiff UMB Bank, N.A., solely in its capacity as Trustee (“UMB” or the “Trustee”) under the Contingent Value Rights Agreement dated November 20, 2019 (the “CVR Agreement”), by and between Bristol-Myers Squibb Company (“Bristol-Myers”) and UMB’s predecessor Equiniti Trust Company, now known as Equiniti Trust Company, LLC (“Equiniti”), alleges as follows:

**NATURE OF ACTION**

1. Bristol-Myers delayed the Food and Drug Administration’s (“FDA”) approval of lisocabtagene maraleucel (“Liso-cel”), a life-saving cancer therapy that treats the most common form of non-Hodgkin’s lymphoma, eliminating its \$6.7 billion liability under the CVR Agreement. In so doing, Bristol-Myers breached the CVR Agreement, which requires Bristol-Myers to use “Diligent Efforts” to secure approval from the FDA for Liso-cel by December 31, 2020. This suit seeks to hold Bristol-Myers accountable under the CVR Agreement for its blatant failure to use Diligent Efforts and its obstruction of the CVR holders’ power to appoint and direct a Trustee, in breach of the CVR Agreement.

2. Bristol-Myers's \$6.7 billion obligation under the CVR Agreement arises from its November 2019 acquisition of Celgene Corporation ("Celgene"), the pharmaceutical company that developed Liso-cel, also known as JCAR017 and by the trade name Breyanzi. Liso-cel is prescribed for patients suffering from notoriously aggressive large cell non-Hodgkin's lymphoma who are not treated effectively by initial treatments or have relapses. Liso-cel is perceived to have lesser toxicity than other available treatments for patients with persistent lymphoma and to be particularly suitable for those who are older or frail. Time is of the essence for such patients.

3. The merger and CVR Agreement were announced in January 2019, following approximately six months of negotiations between Bristol-Myers and Celgene, in which the primary impediment to the merger was disagreement over Celgene's value. Bristol-Myers proposed the CVR Agreement as a way to bridge the valuation gap: for each share of Celgene stock, the holder would receive a contingent value right ("CVR") requiring Bristol-Myers to pay \$9 (the "Milestone Payment")—amounting to \$6.7 billion in total—if the FDA approved the marketing applications, known as Biologics License Applications ("BLAs") or New Drug Applications, for three Celgene therapies—Liso-cel, the multiple sclerosis therapy Ozanimod, and the multiple myeloma therapy Ide-cel—by certain contractually set dates. Specifically, if the FDA approved (i) Liso-cel by December 31, 2020; (ii) Ozanimod by the same date; and (iii) Ide-cel by March 31, 2021 (collectively, the "Milestones"), then Bristol-Myers was obligated to pay \$6.7 billion to CVR holders as part of its consideration for the acquired company.<sup>1</sup> If Bristol-Myers failed to achieve any Milestone, even by a day, it would pay \$0.

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<sup>1</sup> This figure is based on the number of CVRs listed in the security register as of December 31, 2020.

4. The CVR Agreement’s binary structure, in the absence of provisions to protect the CVR holders’ right to payment, created a perverse economic incentive: if Bristol-Myers delayed at least one of the three therapies to miss a Milestone, it could rely on the resulting delay to argue it had eliminated its entire \$6.7 billion liability. If Bristol-Myers’s gambit were successful, it would obtain Celgene at a windfall market discount.

5. To protect the CVR holders, and to ensure that Bristol-Myers worked towards securing FDA approval for these life-saving therapies before the Milestones, the CVR Agreement required Bristol-Myers to “use Diligent Efforts to achieve the Milestone[s].” This requirement meant that Bristol-Myers had to use the “efforts of a Person to carry out its obligations in a diligent manner using such effort and employing such resources normally used by such Person in the exercise of its reasonable business discretion relating to the research, development or commercialization of a product[] that is of similar market potential at a similar stage in its development or product life.”

6. Prior to the merger, when Celgene controlled Liso-cel and Ide-cel, these treatments were on the fast track for approval. The FDA had designated both as Breakthrough Therapies and had designated Liso-cel as a Regenerative Medicine Advanced Therapy. These designations ensured an expedited development and review process. The FDA committed to provide intensive, interactive guidance during both therapies’ development—with senior FDA personnel involved in a proactive, collaborative review of the therapies—so that both therapies could enter the market quickly and safely to begin saving patients’ lives. The FDA again recognized Liso-cel’s critical importance to patients by granting it Priority Review status on February 13, 2020. Priority Review status shortens the Prescription Drug User Fee Act (“PDUFA”) date, the FDA’s target date for issuing a decision on a BLA, from ten months to six months. For BLAs with Priority Review, the

FDA meets the PDUFA date nearly 100% of the time. The PDUFA date for Liso-cel was August 17, 2020, comfortably four months before the Liso-cel Milestone.

7. The momentum towards approval that Celgene built was lost after Bristol-Myers assumed control. Bristol-Myers failed to use Diligent Efforts to achieve those Milestones, and the FDA approval process for Liso-cel and Ide-cel began to suffer setbacks. Bristol-Myers made a highly atypical decision to exclude critical and mandatory information in its initial filing of the Liso-cel BLA. It excluded data on critical tests needed to demonstrate the safety and efficacy of Liso-cel. Bristol-Myers also withheld details concerning the procedures it used to ensure the tests were valid. Bristol-Myers belatedly submitted this information through a “major amendment” to its BLA filed on April 15, 2020—two months after the FDA had accepted Bristol-Myers’s BLA for review and set the August 17, 2020 PDUFA date. This “major amendment” automatically extended the PDUFA date by three months to November 17, 2020. That placed the FDA’s target approval date perilously close to the December 31, 2020 Liso-cel Milestone.

8. At almost the same time, Bristol-Myers was also improperly delaying the approval process for Ide-cel. On May 13, 2020, following an initial review of the Ide-cel BLA, the FDA determined that the Ide-cel BLA was so materially deficient that the FDA took the exceedingly rare step of rejecting the Ide-cel BLA entirely.

9. Bristol-Myers’s violation of its contractual obligation to use Diligent Efforts did not stop there. Given the delay the major amendment caused for the approval of the Liso-cel BLA, if it were to meet the contractually agreed Milestones set forth in the CVR Agreement, it was critical that Bristol-Myers ensure that the rest of the FDA approval process proceeded smoothly. Instead, Bristol-Myers failed to take the steps necessary to prepare two Liso-cel manufacturing facilities for the FDA’s inspections.

10. From October 7, 2020 to October 16, 2020, the FDA inspected a Bristol-Myers facility in Bothell, Washington (the “Juno Facility”) where Bristol-Myers produces Liso-cel. Even though Bristol-Myers had advance notice of the inspection, it inadequately prepared the Juno Facility, and the FDA inspectors found numerous, substantial deviations from known or readily determinable FDA regulations and guidelines. For example, the FDA found that Bristol-Myers had failed to: (i) implement appropriate procedures to ensure batches of Liso-cel conformed to appropriate quality standards; (ii) explain and document discrepancies between batches of Liso-cel; and (iii) monitor the manufacturing environment to prevent the contamination of sterile drug products. Weeks later, Bristol-Myers responded to the FDA’s findings, admitting that it would need to take remedial actions to improve its operations and quality control systems to comply with FDA regulations and guidelines. But the FDA found that even this response by Bristol-Myers contained “unclear and questionable points,” resulting in more than a month of further delay. Ultimately, Bristol-Myers failed to provide an adequate response to the FDA’s findings until December 18, 2020, just days before the Liso-cel Milestone.

11. From December 3, 2020 to December 10, 2020, the FDA performed an inspection of a facility in Houston, Texas owned by Lonza Group AG (the “Lonza Facility”), where a critical component of Liso-cel is manufactured. Bristol-Myers, as the manufacturer of Liso-cel, was responsible for ensuring that the Lonza Facility’s practices complied with FDA requirements. Despite Bristol-Myers’s prior experience and failings, including having the benefit of the findings from the Juno Facility inspection in October 2020, it still failed to ensure that the Lonza Facility complied with FDA requirements. The FDA’s inspection of the Lonza Facility revealed numerous, egregious deviations from FDA regulations and guidelines—many of which mirrored the unacceptable conditions and procedures the FDA noted in the Juno Facility. For example, the FDA

found rudimentary deficiencies including insufficient controls to check for microbiological contamination of sterile materials at the Juno Facility; the FDA observed similar inadequate controls to prevent microbial contamination at the Lonza Facility. And although Bristol-Myers knew from the inspection of the Juno Facility that its procedures for inspecting raw materials were deficient, the FDA cited the Lonza Facility for failing to inspect raw materials at all.

12. The FDA identified numerous other egregious violations at the Lonza Facility that occurred under Bristol-Myers's control. The FDA found: (i) poorly maintained and carelessly organized freezer bins full of overturned and frosted-over bottles; (ii) unlocked freezer bins containing material that was supposed to be quarantined; and (iii) material that had expired more than seven months earlier that was never discarded. The FDA also reported that Bristol-Myers failed to institute procedures to prevent serious quality control errors. For instance, materials that passed quality control were labeled with the very same color and text as material that had been rejected, creating a high likelihood of confusion between the two. Similarly, material that had been rejected by quality control was stored in the same freezer as material that had passed quality control, and material intended for use within the United States were stored in the very same freezer as material intended for foreign markets with different manufacturing standards.

13. As news of these mishandled inspections and further delays reached the public, certain CVR holders became concerned that Bristol-Myers was failing to exercise the diligence required under the CVR Agreement. The CVR Agreement provides that the Trustee shall enforce such breaches against Bristol-Myers and allows a majority of holders to appoint a Trustee of their choosing at any time. On December 18, 2020, a majority of CVR holders executed an Instrument of Removal, Appointment and Acceptance to appoint UMB as their Trustee, effective immediately, and delivered it to Bristol-Myers and Equiniti, the Trustee under the CVR Agreement at the

time. Shortly after, Equiniti sent a notice to Holders signed by Bristol-Myers's Corporate Secretary announcing that UMB had replaced Equiniti as Trustee.

14. UMB sought to inspect Bristol-Myers's books and records on behalf of the CVR holders to assess whether Bristol-Myers was satisfying its obligation under the CVR Agreement to pursue the Milestones for Liso-cel and Ide-cel diligently, or whether there was evidence that Bristol-Myers had failed to do so purposefully or ineptly. On December 29, 2020, UMB demanded to review Bristol-Myers's relevant books and records. Bristol-Myers refused to comply.

15. On December 31, 2020, the Liso-cel Milestone lapsed with Bristol-Myers having failed to secure FDA approval.

16. Aware that UMB was investigating its failure to achieve the Milestone, Bristol-Myers attempted to subvert the CVR Agreement's enforcement provisions and undermine the CVR holders' rights to hold Bristol-Myers accountable for its breach. Even though it knew that litigation over its breach of the Diligent Efforts provision was imminent, and even though the CVR Agreement explicitly states that its termination "*shall not* relieve any Party of any liability arising from any material breach of its obligations" under the Agreement, Bristol-Myers adopted the indefensible position that because portions of the CVR Agreement terminated on December 31, 2020, it could not be held accountable for its breach and that the CVRs were therefore extinguished, worthless, and void.

17. On January 1, 2021—one day after Bristol-Myers missed the Liso-cel Milestone—Bristol-Myers issued a press release memorializing its position that "on January 1, 2021, the Contingent Value Rights Agreement ... terminated automatically in accordance with its terms and the CVRs are no longer eligible for payment under the CVR Agreement."

18. Bristol-Myers then moved immediately, and over UMB’s objection, to instruct the New York Stock Exchange (“NYSE”) to delist the CVRs on the false basis that the CVRs had been “extinguished.” During those communications, Bristol-Myers falsely told the NYSE that “all rights pertaining to the CVRs were extinguished by the automatic termination of the CVR Agreement in accordance with its terms”—even though the CVR Agreement expressly states otherwise. Most notably, the Trustee’s right to enforce the Agreement as against Bristol-Myers’s breaches expressly survived. *See UMB Bank, N.A. v. Bristol-Myers Squibb Co.*, No. 21-CV-4897 (JMF), 2022 WL 2290609, at \*2-3 (S.D.N.Y. June 24, 2022).

19. In breach of its obligation under the CVR Agreement to cause a Security Register to be maintained, and to further undermine the CVR holders’ ability to protect their rights, on January 11, 2021, Bristol-Myers directed the Depository Trust Corporation (“DTC”), which is the registered Holder for 99% of the CVRs, to “delete its entire position” of CVRs from its electronic system on the same false premise, asserting that that the CVRs were “void” and “worthless.” The DTC is a custodian and depository that exists for the purpose of facilitating electronic trading among its participant banks, which hold CVRs on behalf of beneficial holders. The DTC does not vote shares or take any other economic actions for the securities it holds. It acts as the Registered Holder, and grants beneficial holders proxies to act as Registered Holders for their shares when directed. Thus, by directing the DTC to delete the CVRs from its electronic system, Bristol-Myers sought to block CVR holders from using the DTC’s system. This Court held that CVR holders were required to seek authority from the DTC to act as Holders under the CVR Agreement.<sup>2</sup> Once

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<sup>2</sup> UMB has filed a Notice of Appeal of the Court’s order granting Bristol-Myers’s second motion to dismiss. Notice of Appeal, *UMB Bank, N.A. v. Bristol-Myers Squibb Co.*, No. 21-CV-4897 (JMF) (S.D.N.Y. Oct. 29, 2024), ECF No. 172. Nothing in this Complaint should be construed as a waiver of any arguments to be asserted in that appeal.



the DTC complied with Bristol-Myers's demand in January 2021, CVR holders could no longer go to the DTC as the registered Holder to obtain present day authorizations.

20. A few weeks later, on February 5, 2021, Bristol-Myers obtained FDA approval of Liso-cel—just thirty-six days after the Milestone lapsed. Had Bristol-Myers used Diligent Efforts, it would have avoided much more than thirty-six days of delay caused by, among other things, submitting the major amendment to supplement its inadequate BLA, failing to properly operate and prepare the Juno and Lonza Facilities to meet FDA approval requirements, and providing an inadequate response to the FDA's findings at the Juno Facility.

21. Other cellular therapies based on similar technology have received FDA approval without the issues and ineptitude that plagued Bristol-Myers, and in substantially less time. For example, the Gilead Sciences ("Gilead") therapy Yescarta and the Novartis International AG ("Novartis") therapy Kymriah—both cellular therapies that, like Liso-cel, treat lymphoma—were approved in less than half the time. Another similar lymphoma therapy, Gilead's Tecartus, was submitted for FDA review just one week before Liso-cel but was approved more than six months sooner. Had Bristol-Myers used Diligent Efforts as required under the CVR Agreement, it would have avoided the thirty-six-day delay, and the Liso-cel Milestone would have been achieved.

22. With the Liso-cel Milestone missed and the CVRs delisted, Bristol-Myers no longer needed Ide-cel to miss its Milestone for it to assert that it had no obligation to pay \$6.7 billion to the CVR holders. Bristol-Myers's lack of Diligent Efforts had taken the Ide-cel approval process right up to the deadline, with the FDA approving the Ide-cel BLA on March 26, 2021, just five days before the Ide-cel Milestone under the CVR Agreement.

23. Thus, Bristol-Myers achieved two of the three Milestones, with only the Liso-cel Milestone left unfulfilled. Had Bristol-Myers made Diligent Efforts to achieve the Liso-cel Milestone, it would have been required to pay \$6.7 billion to the CVR holders. Bristol-Myers's failure to exercise Diligent Efforts has, to date, allowed it to take control of three FDA-approved blockbuster therapies—Liso-cel, Ozanimod, and Ide-cel—at an enormous discount and at the CVR holders' expense. Bristol-Myers almost immediately put this windfall to use, announcing on February 4, 2021 the repurchase of \$4 billion in debt.

24. On June 3, 2021, UMB sued Bristol-Myers asserting claims on behalf of CVR holders similar to those asserted here. In its first motion to dismiss, Bristol-Myers wrongly argued that the Trustee's ability to notice an Event of Default and enforce the Agreement "terminated" on January 1, 2021. The Court rejected this position on June 24, 2022, denying Bristol-Myers's motion. *UMB Bank, N.A.*, 2022 WL 2290609, at \*2-3.<sup>3</sup> As part of that decision, the Court noted that "the CVR Agreement explicitly provides that Article 8, which empowers [the Trustee] to bring suit, 'shall survive termination of this CVR Agreement' and that 'the termination of this CVR Agreement shall not relieve any Party of any liability arising from any material breach of its obligations under this CVR Agreement occurring prior to the Termination Date.'" *Id.*

25. Yet despite the Court's rejection of its argument, to this day Bristol-Myers continues to inform holders on its website that "[b]ecause the milestone of approval of [L]iso-cel by December 31, 2020 was not met, the CVR agreement has automatically terminated in accordance with its terms ... and the CVRs are no longer eligible for payment." Acquisition FAQs

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<sup>3</sup> Bristol-Myers noticed its intent to appeal this decision on November 6, 2024. Notice of Cross Appeal, *UMB Bank, N.A. v. Bristol-Myers Squibb Co.*, No. 21-CV-4897 (JMF) (S.D.N.Y. Nov. 6, 2024), ECF No. 173.

for Celgene shareholders, Bristol Myers Squibb, <https://www.bms.com/investors/shareholder-services/shareholder-faq.html> (last visited Feb. 3, 2025).

26. Following the denial of Bristol-Myers's motion to dismiss, the case then proceeded to fact and expert discovery. At the close of extensive fact discovery and over two years into the case, in October 2023, Bristol-Myers sought to file a second motion to dismiss arguing that UMB had not been appointed as Trustee because the CVR holders had not obtained proxies from the DTC.

27. During the briefing of that motion, CVR holders obtained proxies from Cede & Co., the DTC's nominee and the registered Holder for those holders' CVRs, which confirm UMB's replacement of Equiniti as Trustee in December 2020 (the "Confirmation"). While the Court held that UMB was not the Trustee at the time the June 3, 2021 complaint was filed and dismissed the case on that basis without prejudice, it left open the question of whether the Confirmation establishes UMB as Trustee.

28. After the Court dismissed UMB's initial case on the ground that the CVR holders were required to obtain DTC authorization to act, certain CVR holders directly, and through the DTC participant banks that held their shares, approached the DTC to determine whether it could revive the CVRs in its system. DTC confirmed that it could, in principle, take this action and put the system back to where it was in January 2021, but that it would only do so at the direction of Bristol-Myers. Bristol-Myers however, takes the untenable position that rights of Holders to vote or act terminated on January 1, 2021 with the expiration of the Liso-cel Milestone, even though Article 8 of the CVR Agreement expressly authorizes enforcement after this date, and provides for enforcement mechanisms.

29. Despite Bristol-Myers's attempt to undermine the CVR holders' ability to exercise their voting rights from January 2021 until the present, the Confirmation established UMB as the Trustee. UMB thus now asserts its claims against Bristol-Myers anew. UMB also requests a declaratory judgment against Bristol-Myers and Equiniti that (i) the Confirmation was effective and that UMB is the Trustee under the CVR Agreement; and (ii) Equiniti is no longer the Trustee under the CVR Agreement.

30. UMB further asserts that Bristol-Myers breached its obligation under Section 3.5(a) of the CVR Agreement to cause a Security Register to be maintained and that Bristol-Myers breached its duty of good faith and fair dealing by instructing the DTC to "delete" its system for tracking holdings in CVRs and seeks an order directing Bristol-Myers to specifically perform its obligations under Section 3.5(a) and direct the DTC to reinstate the CVRs, and excusing performance of any provision of the CVR Agreement that requires utilization of the Security Register until such Security Register is established and the DTC has reinstated the CVRs. In the alternative, UMB seeks a declaratory judgment that Bristol-Myers's actions have thwarted the ability of the CVR holders to satisfy any requirement in the CVR Agreement which requires a beneficial CVR holder to obtain a proxy from its Registered Holder, and that any such requirement is excused.

#### **JURISDICTION, VENUE, AND GOVERNING LAW**

31. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, and the amount in controversy for each claim separately, exclusive of interest and costs, exceeds \$75,000. Bristol-Myers breached the Diligent Efforts provision, and Count II seeks damages for that breach in excess of \$6.7 billion. A declaration that UMB is the Trustee under the CVR Agreement (Count I) necessarily concerns over \$75,000 because the Trustee is the party authorized to pursue the claim against Bristol-Myers for breach of the Diligent Efforts provision.

UMB, as Trustee, has also incurred and will incur more than \$75,000 in expenses to pursue the CVR holders' claim for Bristol-Myers' breach of the Diligent Efforts provision, pursuant to Section 4.7 of the CVR Agreement. Counts III, IV, and V also concern over \$75,000 because they seek relief that would allow the CVR holders to pursue their claim against Bristol-Myers for its breach of the Diligent Efforts provision.

32. UMB has standing to pursue this action because it succeeded Equiniti as Trustee of an express trust for the benefit of the holders of CVRs under the CVR Agreement.

33. Section 4.10(c) of the CVR Agreement states that "[t]he Trustee may be removed at any time by an act of the Majority Holders, delivered to the Trustee and to the Company." Ex. A § 4.10(c). Section 4.10(e) provides: "If, within one year after any ... removal ..., a successor Trustee shall be appointed by act of the Majority Holders delivered to [Bristol-Myers] and the retiring Trustee, then the successor Trustee so appointed shall ... become the successor Trustee and supersede the successor Trustee appointed by [Bristol-Myers]." *Id.* § 4.10(e). Section 4.11(a) requires a successor Trustee to "execute, acknowledge and deliver to [Bristol-Myers] and to the retiring Trustee an instrument accepting such appointment," at which point "the resignation or removal of the retiring Trustee shall become effective and such successor Trustee, without any further act, deed or conveyance, shall become vested with all the rights, powers, trusts and duties of the retiring Trustee." *Id.* § 4.11(a).

34. On December 18, 2020, pursuant to Sections 4.10(c), 4.10(e), and 4.11(a) of the CVR Agreement, UMB delivered to Bristol-Myers and Equiniti an "Instrument of Removal, Appointment and Acceptance" (the "Instrument"), which stated that "Holders of not less than 50% of the principal amount of CVRs outstanding have removed Equiniti as trustee under the [CVR] Agreement, and appointed UMB Bank, National Association as successor trustee." Ex. D. The

Instrument was signed by CVR holders who, as of December 9, 2020, held their CVRs with DTC participant banks or custodians who held the CVRs in custody with the DTC. *Id.*<sup>4</sup>

35. On December 31, 2020, UMB provided Equiniti and Bristol-Myers account statements from DTC participant banks or custodians for a majority of CVR holders as proof of their holdings. Ex. E. These account statements included statements of CVR holders who signed the Instrument submitted on December 18, 2020, and additional holders who subsequently joined the Instrument. Along with these account statements, UMB delivered additional signature pages for CVR holders (as of December 9 and 18, 2020), joining the Instrument. Equiniti reviewed these statements and concluded that a majority of CVR holders had presented proof sufficient to replace Equiniti with UMB as Trustee.

36. On January 4, 2021, Equiniti distributed a Notice to Holders from Bristol-Myers stating that Equiniti had been replaced as Trustee by UMB. Ex. F. Bristol-Myers did not object to the validity of the Instrument within 120 days of December 9 or December 18, 2020. Indeed, Bristol-Myers did not raise the absence of DTC authorization for the Instrument until nearly three years later. Once Equiniti accepted the Instrument and, at Bristol-Myers' direction, notified Holders that UMB was the Trustee, the CVR holders relied on the appointment for more than 120 days.

37. Since January 4, 2021, UMB has been acting diligently to protect the interests of all CVR holders. UMB investigated claims against Bristol-Myers to hold it accountable for its failure to pay over \$6.7 billion to CVR holders as a result of its failure to use Diligent Efforts to

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<sup>4</sup> CVR holders worked through the holidays to replace Equiniti before January 1, 2021, because they knew that Bristol-Myers would wrongfully assert that after that date the CVR Agreement had terminated and the CVR holders had no right to replace the Trustee or enforce their rights. Bristol-Myers ultimately took that position. *See infra* ¶¶ 112-14, 116, 121-23. In addition, the CVR holders believed it was important to appoint an experienced trustee promptly in light of the rapidly approaching Milestone date.

meet the Milestones. To bring suit, UMB explored funding options from multiple parties before executing the Prepaid Forward Agreement, the vehicle through which a majority of CVR holders have funded litigation fees and costs related to prosecuting their rights under the CVR Agreement.

38. On June 3, 2021, UMB filed claims against Bristol-Myers for violation of its obligations under the CVR Agreement. *See UMB Bank, N.A. v. Bristol-Myers Squibb Co.*, No. 21-CV-04897 (S.D.N.Y. filed June 3, 2021) (the “Litigation”). UMB discharged the responsibilities of the Trustee, overseeing the Litigation. As Bristol-Myers testified during its 30(b)(6) deposition in the Litigation, no beneficial holder or Holder other than Bristol-Myers has objected to UMB’s appointment as Trustee under the CVR Agreement.

39. On February 2, 2024, Bristol-Myers filed a second motion to dismiss the Litigation for lack of standing, asserting that UMB was not the Trustee because the Instrument was effected by beneficial CVR holders and not “Holders.” Bristol-Myers argued that proxies from the DTC were necessary to establish the CVR holders as Holders to appoint UMB as Trustee. Bristol-Myers also argued in its motion that the Instrument should have set December 18, 2020 as the record date for a vote.

40. Bristol-Myers asserts that Equiniti was never replaced and is still the Trustee, notwithstanding Equiniti’s sworn testimony on January 22, 2024, that it was not the Trustee under the CVR Agreement.

41. By April 17, 2024, before a ruling on Bristol-Myers’s second motion to dismiss, a majority of CVR holders who held CVRs as of both December 9, 2020 and December 18, 2020, obtained proxies (“DTC Confirmations”) to assert all the rights of Cede & Co., as the DTC’s nominee and the Holder on the Security Register. CVR holders asked their prime brokers or other CVR custodians who are the DTC participants to send instruction letters to the DTC asking it to

cause Cede & Co. to authorize the CVR holders to take any and all actions that Cede & Co. is able to take under the CVR Agreement as of December 9, 2020 and December 18, 2020. The DTC complied with these instructions and returned the signed proxy letters from Cede & Co. to the DTC participants, who then returned them to the relevant CVR holders.

42. When CVR holders holding a majority of Outstanding CVRs obtained completed proxy letters from DTC on April 17, 2024, UMB filed such proxies with the Court in the Litigation on that day.<sup>5</sup> UMB continued to receive proxies from the DTC for additional CVR holders and filed such supplemental proxies with the Court in the Litigation on April 29, 2024. UMB continued to receive additional proxies after briefing on the motion closed. The Court granted UMB leave to file additional DTC proxies during oral argument on the motion and UMB did so on September 10, 2024.

43. As of the September 10, 2024 filing, UMB had received DTC Confirmations for 392,525,875 CVRs, or 52.76% of outstanding CVRs as of December 9, 2020. Ex. G.

44. As of the September 10, 2024 filing, UMB had received DTC Confirmations for 394,630,734 CVRs, or 53.05% of outstanding CVRs as of December 18, 2020. Ex. H.

45. Holders comprising approximately 1% of outstanding CVRs who held their CVRs on December 9 and 18, 2020 but did not participate in the Instrument in December 2020, completed DTC Confirmations and joined the Instrument in 2024. Ex. I.

46. Some CVR holders did not obtain DTC proxies in 2024 for 100% of the shares they held on December 9 and 18, 2020, because the passage of time made it challenging for certain DTC participant banks and custodians to confirm all of their holdings. For this reason, several of

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<sup>5</sup> UMB has demonstrated a majority based on a total number of Outstanding CVRs—*i.e.*, CVRs issued under the CVR Agreement excluding those held by Bristol-Myers or its affiliates, CVR Agreement §1.1— 743,914,518. ECF No. 77-25.



the DTC authorizations are for a smaller number of CVRs than listed on the signature pages for the Instrument. UMB does not rely on shares held by CVR holders who executed the Instrument, which were not authorized in the DTC Confirmations. The total number of CVRs in the DTC Confirmations constitutes a majority of Outstanding CVRs as of December 9 and 18, 2020. *See* Ex. R.

47. On September 30, 2024, the Court granted Bristol-Myers’s second motion to dismiss on the basis that the CVR holders did not obtain DTC proxies before UMB filed suit. Because UMB did not replace Equiniti as Trustee before UMB filed suit on June 3, 2021, the Court found that UMB did not have standing when it filed the Litigation. The Court did not address whether the DTC Confirmations that UMB received after filing the Litigation later established UMB as the Trustee. The Court held that “the question of who the Trustee is now—namely, whether it is still Equiniti or, as a result of the ‘reconfirmation’ process earlier this year, whether it is now UMB” was “a question for another day,” noting that it was the Court’s expectation that “simply a new case would be filed,” which would “pick up where [the first case] left off.” Ex. J at 71:25-72:1.

48. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2).

49. Pursuant to Section 1.10 of the CVR Agreement, which expressly survives termination, Bristol-Myers and the Trustee agreed to submit to the exclusive jurisdiction and venue of any state or federal court in Manhattan, New York.

50. Pursuant to Section 1.10 of the CVR Agreement, New York law applies to this action.

### **THE PARTIES**

51. Plaintiff UMB is a federally chartered national banking association with its main office, as listed in its articles of association, in Kansas City, Missouri and is the Trustee under the CVR Agreement.

52. Defendant Bristol-Myers is a global biopharmaceutical company incorporated in the state of Delaware and headquartered in Lawrenceville, New Jersey.

53. Defendant Equiniti Trust Company, LLC is the successor in interest to Equiniti Trust Company, the original Trustee under the CVR Agreement, under the terms of a 2023 merger between Equiniti Trust Company and American Stock & Transfer Company LLC. Defendant Equiniti Trust Company, LLC is a limited liability company organized under the laws of the state of New York. Equiniti Trust Company, LLC's sole member is Armor II Holding, LLC, a limited liability company organized under the laws of the state of New York. Armor Holding II, LLC's sole member is Armor Intermediate Company, LLC, a limited liability company organized under the laws of the state of Delaware. Armor Intermediate Company, LLC's sole member is Armor Holdco, Inc., a Delaware corporation with its principal place of business in New York.

### **FACTUAL ALLEGATIONS**

#### **I. Bristol-Myers Acquires Celgene, The Developer Of Liso-Cel, And Issues Contingent Value Rights To Bridge The Gap On The Merger Price**

54. In September 2018, Bristol-Myers, an international pharmaceutical company, proposed a merger with its competitor Celgene that would result in Celgene becoming a wholly owned subsidiary of Bristol-Myers. The merger negotiations stretched over approximately six months, with Celgene's valuation the main point of contention.

55. On December 27, 2018, to bridge this valuation gap, Bristol-Myers proposed issuing a CVR to Celgene stockholders as additional consideration for their shares. A CVR is a security that generally requires the issuer to make a payment to the holder of the security if contractually specified events occur by contractually specified dates. The initial proposal did not list all terms, but Celgene notified Bristol-Myers that it would accept the proposal so long as the CVR

Agreement's terms were "clear, tied to near-term events, and aligned with the strategy of the combined company."

56. Intense negotiations over the terms of the potential CVR Agreement followed, including the amount that would be paid to Celgene stockholders and the events that would need to occur for the CVRs to become payable.

57. Bristol-Myers and Celgene ultimately agreed that each CVR would carry a one-time \$9 payment, contingent on the FDA approving the marketing applications, known as Biologics License Applications (or BLAs) for biologics and New Drug Applications for drugs,<sup>6</sup> for three Celgene products (collectively, the "Milestone Therapies")—(i) Liso-cel, which treats diffuse large B-cell non-Hodgkin's lymphoma; (ii) Ozanimod, which treats relapsing multiple sclerosis; and (iii) Ide-cel, which treats relapsed and refractory multiple myeloma. The \$9 per CVR payment was contingent on each of those Milestones being achieved by contractually specified dates.

58. The dates for the Milestones were vigorously negotiated. The contracting parties agreed to deadlines that both sides believed were achievable: December 31, 2020 for Liso-cel and Ozanimod, and March 31, 2021 for Ide-cel. If all three Milestone Therapies were approved by their respective Milestones, Bristol-Myers would owe the CVR holders a total of \$6.7 billion. If any Milestone were missed, Bristol-Myers would owe the CVR holders nothing.

59. The binary structure of the CVRs created perverse economic incentives for Bristol-Myers: Once the merger became effective, Bristol-Myers would control the remaining development and marketing approval process for the Milestone Therapies, so it could effectively eliminate a \$6.7 billion liability by slightly delaying the approval process for any of the Milestone Therapies

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<sup>6</sup> Therapies referred to as drugs tend to be chemically synthesized and have a known chemical structure, whereas biologics are normally derived from the human body and generally do not have a known structure.

and still retain substantially all the upside of the three Milestone Therapies. A delay of a few weeks, or even a few months, would have minimal impact on Bristol-Myers's ultimate profits from selling the Milestone Therapies but could be used to argue that Bristol-Myers had eliminated its \$6.7 billion payment obligation.

60. To protect the CVR holders from Bristol-Myers's ability to manipulate the timeline for its exclusive benefit, the CVR Agreement requires Bristol-Myers to "use Diligent Efforts to achieve the Milestone[s]." Ex. A § 7.8. The CVR Agreement defines "Diligent Efforts" to mean, in relevant part, the "efforts of a Person to carry out its obligations in a diligent manner using such effort and employing such resources normally used by such Person in the exercise of its reasonable business discretion relating to the research, development or commercialization of a product, that is of similar market potential at a similar stage in its development or product life." *Id.* § 1.1. Thus, Bristol-Myers could not take steps to delay FDA approval of the Milestone Therapies or sit idly by when the FDA raised serious issues that could delay approval—either would be a breach of its obligation under the CVR Agreement to use Diligent Efforts to achieve the Milestones.

61. Bristol-Myers controlled much of the information relevant to determining whether Bristol-Myers complied with the CVR Agreement, including its covenant to use Diligent Efforts to achieve the Milestones. Thus, the CVR Agreement includes two provisions designed to create accountability and prevent Bristol-Myers from erasing its obligations by failing to generate or obscuring information that might reveal its defaults. First, the CVR Agreement requires Bristol-Myers and its subsidiaries to "use commercially reasonable efforts ... to keep true, complete and accurate records in reasonably sufficient detail to enable the [CVR] Holders to determine if [Bristol-Myers] has complied with its obligations under th[e] CVR Agreement." *Id.* § 7.5. Second, the CVR Agreement authorizes the Trustee to obtain those records. Specifically, the CVR Agreement

states that the Trustee “shall be entitled to examine the pertinent books and records of [Bristol-Myers]” to investigate “the facts or matters stated in any ... statement, ... opinion, report, notice ... or other paper or document.” *Id.* § 4.2(f).

62. On January 3, 2019, Bristol-Myers and Celgene executed the merger agreement. For each outstanding Celgene share, Celgene shareholders received one share of Bristol-Myers common stock, \$50 cash, and one CVR. Bristol-Myers announced that the merger would “creat[e] a leading focused biopharma company,” which, among other things would be “positioned for long term leadership in hematology.” Bristol-Myers stated that Liso-cel and Ide-cel were “high value near-term assets,” and that Liso-cel, Ozanimod, and Ide-cel were three of “six near-term product launch opportunities with potential for greater than \$15 [billion] in revenue.” Bristol-Myers noted that the acquisition would yield approximately \$45 billion in “free cash flow” for the first three years, and that it “expect[ed] to fulfill [the] CVR obligation with ongoing cash flow.”

63. Bristol-Myers and Celgene shareholders approved the merger on April 12, 2019.

64. Both the merger and the CVR Agreement became effective on November 20, 2019.

## **II. Before Bristol-Myers’s Substantial Involvement, Liso-cel Was On The Fast Track For Approval**

65. Before the merger, all three Milestone Therapies were on the fast track for approval well ahead of the Milestones, including Liso-cel. Liso-cel, also known as JCAR017 and by its trade name Breyanzi, is a lifesaving therapy for a highly vulnerable set of patients with advanced-stage cancer. It is a chimeric antigen receptor T-cell therapy (“CAR-T Therapy”) that treats patients with diffuse large B-cell non-Hodgkin’s lymphoma, which is the most common non-Hodgkin’s lymphoma. Liso-cel is used to treat patients for whom prior courses of treatment have failed. Like other CAR-T Therapies, Liso-cel treats this terminal disease by extracting a cancer patient’s T-cells, which are white blood cells that kill infected or cancerous cells, genetically modifying

them to target and kill B-cells that have become malignant, and then injecting the genetically modified T-cells into the patient, where they attack and kill malignant B-cells.

66. Although Liso-cel is not the first FDA-approved CAR-T Therapy for diffuse large B-cell non-Hodgkin's lymphoma—Novartis received FDA approval for Kymriah in August 2017 and Gilead received FDA approval for Yescarta in October 2017—it is the most effective. Patients treated with Liso-cel have a remarkable overall response rate of 73% (meaning that in 73% of cases, the patient's cancer reduces) and have a complete response of 54% (meaning that in 54% of cases, all signs of cancer disappear). Kymriah and Yescarta both have lower overall response rates and complete response rates.

67. Liso-cel's demonstrated efficacy in treating—and in some cases curing—diffuse large B-cell non-Hodgkin's lymphoma caused the FDA to designate it as both a Breakthrough Therapy in 2016 and a Regenerative Medicine Advanced Therapy in 2017. Both designations expedite the development and review process. The FDA designates a therapy as a Breakthrough Therapy only if the therapy is expected to be a substantial improvement over existing treatments of a serious medical condition. The FDA provides a Breakthrough Therapy intensive, interactive guidance during the therapy's development, with senior FDA personnel involved in a proactive, collaborative review of the therapy. Because of the life-saving nature of a Breakthrough Therapy, such a designation allows the FDA to authorize a rolling review of the therapy's marketing application to allow the product to enter the market more quickly.

68. A Regenerative Medicine Advanced Therapy designation provides, in addition to all the same benefits that a Breakthrough Therapy designation offers, broader avenues to accelerate the review process further and to satisfy post-approval requirements. The combined result of the

Breakthrough Therapy and Regenerative Medicine Advanced Therapy designations is an expedited development and review process designed to allow the therapy to reach the market quickly so that it can start saving lives as soon as possible.

69. Liso-cel continued its impressive trajectory following the FDA's designations of Liso-cel as a Breakthrough Therapy and a Regenerative Medicine Advanced Therapy. Clinical trials showed strong overall and complete response rates in patients suffering from diffuse large B-cell non-Hodgkin's lymphoma, and most patients did not experience the two life-threatening side-effects associated with Kymriah and Yescarta, cytokine-release syndrome and neurotoxicity. The FDA concluded the clinical trials were "well-controlled" and "demonstrated high response rates and durability of [complete response] rate."

70. Immediately after the CVR Agreement and the Celgene acquisition became effective, all signs continued to point to an expedited approval track for Liso-cel. Celgene, now fully controlled by Bristol-Myers, completed the filing of the Liso-cel BLA. A BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. Its issuance requires a determination that the product, the manufacturing process, and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity, and potency of the product. The BLA is the last step in the development process before a therapy can be brought to market.

71. To enable the FDA to conduct its review, the BLA must include, among other things, clinical data demonstrating the safety and efficacy of the therapy, information concerning the manufacturing and controls for production, a detailed description of the manufacturing facility,

and the proposed product label. Once the FDA has reviewed the BLA, conducted facilities inspections, and concluded that the therapy is efficacious, safe, and appropriately labeled, the FDA issues its approval.

72. Celgene had submitted the first component of the Liso-cel BLA to the FDA on September 30, 2019, before the merger became effective. But the submission of the most critical section of the BLA—the Chemistry, Manufacturing and Controls (“CMC”) section, which specifies the manufacturing processes, product characteristics, and product testing upon which the manufacturer relies to ensure that its therapy is safe, effective, and consistently manufactured—occurred after the merger closed and Bristol-Myers assumed control. Bristol-Myers did not submit the CMC section until December 18, 2019, nearly a month after the merger became effective on November 20, 2019.

73. Upon the submission of the Liso-cel BLA on December 18, 2019, the FDA had sixty days to conduct an initial review to determine whether the application was complete and—critically—to determine whether to grant Priority Review. The FDA reserves Priority Review for therapies that are significant improvements to the safety or efficacy of the treatment, diagnosis, or prevention of a serious condition.

74. A Priority Review designation provides a substantial benefit to the manufacturer. In general, the FDA commits to endeavor to review and render a decision on a BLA by a set date, known as a PDUFA date. For non-priority BLAs, the FDA sets the PDUFA date at ten months after the FDA completes its initial sixty-day review. For BLAs slated for Priority Review, the FDA shortens the PDUFA date to six months after the initial review.

75. The PDUFA date is of critical importance. The FDA has issued guidance stating that it strives to approve or deny BLAs and New Drug Applications by the PDUFA date at least



90% of the time. In reality, the FDA does even better. For the 155 BLAs and New Molecular Entity New Drug Applications (which are reviewed under the same program) granted Priority Review in fiscal years 2014 through 2018,<sup>7</sup> the FDA made a decision by the PDUFA date in all but three instances, which is 98% of the time. For fiscal years 2016 to 2018, the FDA approved those applications by the PDUFA date 100% of the time.

76. The FDA completed its initial review of the Liso-cel BLA on February 13, 2020 and—because of Liso-cel’s potential to improve non-Hodgkin’s lymphoma treatment significantly—granted it Priority Review, shortening the approval timeline from ten months to just six. This meant that the Liso-cel PDUFA date was August 17, 2020, four and a half months before the December 31, 2020 Liso-cel Milestone.

### **III. Bristol-Myers Engages In Egregious Misconduct That Delays FDA Approval**

#### **A. Bristol-Myers Submits A Major Amendment To The Liso-cel BLA That Delays FDA Approval By At Least Three Months**

77. When Bristol-Myers took control of Liso-cel following the merger, Liso-cel’s development took a sudden and marked turn for the worse. The New Drug Application for Ozanimod, one of the three Milestone Therapies, had been submitted well before the merger closed, and the FDA granted Ozanimod approval on March 26, 2020, shortly after the merger closed. Thus, for Bristol-Myers to have a basis to argue that it did not have a \$6.7 billion liability to CVR holders under the CVR Agreement, it had to delay the FDA approval process for Liso-cel or Ide-cel, both of which were on the fast-track for approval well before their respective Milestones.

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<sup>7</sup> BLAs and New Molecular Entity New Drug Applications are both reviewed under the FDA’s “Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs,” which sets out a defined review process and includes regular meetings between FDA officials and the applications’ sponsors, “to promote the efficiency and effectiveness of the first cycle review process and minimize the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality new drugs and biologics.”

78. That is precisely what Bristol-Myers did. Bristol-Myers's first steps to delay Liso-cel's approval occurred shortly after the merger closed. In the CMC section of the Liso-cel BLA submitted on December 18, 2019, Bristol-Myers made an extremely atypical decision. It chose to omit basic data detailing (i) the tests used to ensure that Liso-cel is safe and efficacious, referred to as assays, and (ii) the studies that assess whether those assays worked as they were supposed to, referred to as validation. These data are rigorously compiled over the course of developing a biologic and are routinely included in BLAs. As Bristol-Myers knew or should have known, they are fundamental components of a BLA, without which the FDA cannot make an informed decision, or any decision, on approval.

79. Predictably, on March 23, 2020, the FDA submitted an information request to Bristol-Myers seeking the missing data on assays and validation. On April 15, 2020, Bristol-Myers amended the CMC section of the BLA to provide the missing data. Within weeks, the FDA concluded what must have been glaringly obvious to Bristol-Myers: the new information Bristol-Myers provided in the amendment was so substantial that it rose to the level of a "major amendment." The "major amendment" designation automatically triggered a three-month extension of the PDUFA date—from August 17, 2020 to November 16, 2020, only weeks before the December 31, 2020 Liso-cel Milestone.

80. Major amendments are rare. Because a major amendment automatically extends the PDUFA date by three months, the FDA will declare a major amendment only if there is a "substantial amount" of new data or new manufacturing or facility information or if there is a new analysis of clinical studies not previously submitted to the FDA.

81. Practice bears out the FDA's reluctance to declare a major amendment. Of the 133 therapies approved in fiscal year 2019, only eighteen had a major amendment. And of the 177

therapies approved in fiscal year 2018, only twenty had a major amendment. The Government Accountability Office reported that from 2014 to 2018, just four out of fifty-three New Drug Applications (the drug equivalent of a BLA) designated for Priority Review had a major amendment filed. A major amendment for a cancer therapy designated as both a Breakthrough Therapy and a Regenerative Medicine Advanced Therapy and selected for Priority Review is exceedingly rare, since the purpose of such designations is to ensure the FDA is deeply involved in the therapy's development. Had Bristol-Myers satisfied its contractual obligation to exercise Diligent Efforts to achieve the Liso-cel Milestone, there would not have been a major amendment or the accompanying delay.

82. The market understood the implication of a major amendment for the Liso-cel Milestone. The CVR, which had been trading at \$4.50 at the end of April 2020, dropped to just \$3.00 in the days following Bristol-Myers's announcement of the major amendment.

**B. The FDA Refuses To Accept Bristol-Myers's Materially Deficient Ide-cel BLA**

83. Bristol-Myers's failure to exercise Diligent Efforts, however, was not isolated to Liso-cel. Bristol-Myers also stalled the development of Ide-cel, the other Milestone Therapy that the FDA had not yet approved. Like Liso-cel, Ide-cel had been granted Breakthrough Therapy designation, putting it on the fast-track to approval.

84. On May 13, 2020, just one week after the FDA recognized Bristol-Myers's Liso-cel amendment as a major amendment, the FDA announced it had issued a refuse-to-file decision for Ide-cel. This decision meant that the BLA Bristol-Myers submitted on March 31, 2020 for Ide-cel was so materially deficient that the FDA would not review it. The FDA issues a refuse-to-file decision only if there is a "clear omission of information or sections of required information," "omission of critical data, information or analyses needed to evaluate safety, purity and potency or provide adequate directions for use," or "[i]nadequate content, presentation, or organization of

information such that substantive and meaningful review is precluded.” Refuse-to-file decisions are exceedingly rare: only 98 out of 2,475 BLAs and New Drug Applications submitted between 2008 and 2017 received a refuse-to-file decision. Such decisions generally reflect an applicant’s unfamiliarity with the basics of the FDA application process, and so are far rarer for major pharmaceutical companies like Bristol-Myers—and rarer still for therapies designated as Breakthrough Therapies or Regenerative Medicine Advanced Therapies. For those few refuse-to-file decisions, FDA review takes substantially longer—approximately sixteen to eighteen additional months—than for BLAs and New Drug Applications that do not receive refuse-to-file decisions.

85. After receiving the refuse-to-file decision, Bristol-Myers did not immediately correct the deficient BLA. Instead, it delayed refiling for over two months, finally resubmitting the BLA on July 31, 2020. This refiling restarted the FDA’s two-month initial review process in which the FDA determines whether the BLA is complete.

86. Had Bristol-Myers satisfied its obligation to exercise Diligent Efforts in submitting an adequate BLA in the first place, the FDA’s formal review process would have commenced by at least May 2020. Because of Bristol-Myers’s lack of Diligent Efforts, the FDA did not start its formal review until September 22, 2020. This avoidable delay does not reflect Diligent Efforts and instead served to increase the odds of missing the Ide-cel Milestone and eliminating a \$6.7 billion obligation to the CVR holders.

**C. Bristol-Myers Fails To Prepare The Liso-cel Manufacturing Facilities, Delaying FDA Approval Further**

87. Bristol-Myers’s misconduct continued during the next step in the Liso-cel BLA review process: the Pre-License Inspections of the Liso-cel manufacturing facilities. A Pre-License Inspection aims to ensure that the facilities used to manufacture a therapy comply with basic FDA safety regulations and requirements.

88. Bristol-Myers knew that the Pre-License Inspections were critical to timely FDA approval of the Liso-cel BLA. The FDA had announced that, in response to the COVID-19 pandemic, it would selectively deploy its resources to inspect manufacturing facilities for BLAs and New Drug Applications. The FDA rescheduled the June 2020 Pre-License Inspections for Liso-cel's manufacturing facilities after the major amendment pushed the PDUFA date three months.

89. Nevertheless, the FDA understood the life-saving importance of Liso-cel, so it rescheduled the Pre-License Inspection for the two facilities involved in the manufacturing of Liso-cel for later in 2020. The two facilities that were to be inspected were the Juno Facility in Bothell, Washington and the Lonza Facility in Houston, Texas. Bristol-Myers completes the production of Liso-cel at the Juno Facility and develops the viral vector—the component of Liso-cel that identifies malignant B-cells—at the Lonza Facility. Bristol-Myers is responsible for ensuring that both facilities comply with FDA regulations, including through monitoring and instructing its contract vendor Lonza concerning FDA compliance.

90. The FDA provides advance notice to manufacturers prior to conducting Pre-License Inspections to give manufacturers the opportunity to fix problems before the inspection and to streamline the Pre-License Inspection process. Bristol-Myers was thus well aware of the upcoming Pre-License Inspections and had ample time to prepare both facilities. But despite this notice and opportunity to prepare, both facilities were woefully unprepared. Shortly after Bristol-Myers acquired Celgene, it described Liso-cel's manufacturing facilities in public presentations as “launch ready.” But after a year of Bristol-Myers's control, those facilities fell short on basic safety and regulatory requirements.

91. The Juno Facility inspection occurred from October 7, 2020 to October 16, 2020. Following that inspection, the FDA issued a Form 483, a form in which the FDA documents “significant” issues identified during an inspection that may violate FDA regulations because they pose a risk that the therapy could be adulterated and harm patients. These observations must be addressed to the FDA’s satisfaction before approval is granted.

92. In the Form 483 for the Juno Facility, the FDA identified numerous, easily avoidable deficiencies. The FDA observed, for example:

- a. Bristol-Myers failed to enforce procedures at the Juno Facility designed to prevent contamination of sterile drug products. Ex. K at 3.
- b. Bristol-Myers had failed to implement laboratory controls with appropriate specifications and procedures to ensure drugs conformed to appropriate standards of identity, strength, quality, and purity. *Id.* at 4.
- c. Bristol-Myers had, on numerous occasions, failed to review discrepancies between batches of Liso-cel—discrepancies that were not properly documented and not properly corrected. *Id.*
- d. Bristol-Myers failed to ensure the reliability of third-party vendors’ Certificates of Analysis, which certify compliance with product specifications. *Id.* at 1.
- e. Bristol-Myers failed to establish appropriate follow-up procedures; for instance, if a Liso-cel batch did not meet specifications, Bristol-Myers did not take appropriate steps to understand why that batch had failed. *Id.*

93. Bristol-Myers’s overt failures to comport with basic FDA standards for safe and reliable manufacturing further delayed the FDA’s approval of Liso-cel. On November 5, 2020, nearly a month after the FDA began its inspection, Bristol-Myers responded to the Form 483 and acknowledged many of the failures the FDA identified. Bristol-Myers stated that it would take actions “to further enhance” its “processes and controls and improve the overall effectiveness of [its] operations and quality system.” But the FDA pointed to “unclear and questionable points” in Bristol-Myers’s response and required Bristol-Myers to supplement its response further. Bristol-Myers did not complete its Form 483 response until December 18, 2020, over two months after

the FDA inspection, a month after the PDUFA date, and a matter of days before the Liso-cel Milestone. The FDA could not complete its review of the Liso-cel BLA until this response was complete. Had Bristol-Myers used Diligent Efforts, such further delay would have been avoided.

94. The host of issues the FDA identified during the Juno Facility inspection should have demonstrated to Bristol-Myers that the Liso-cel BLA was in jeopardy. Bristol-Myers knew or should have known that it needed to make every effort to ensure that the Lonza Facility inspection—the last facility inspection in the FDA approval process—went smoothly. Bristol-Myers did not do so.

95. Following the FDA’s inspection of the Lonza Facility from December 3, 2020 to December 10, 2020, the FDA issued a Form 483 that identified a “litany of errors.” Many of these errors overlapped with similar problems identified during the Juno Facility inspection. For example, during the Juno Facility inspection, the FDA had identified deficiencies in the timing and inspection of raw materials and in the procedures designed to monitor the manufacturing environment for risks of microbiological contamination of purportedly sterile products. Ex. K at 3. During the Lonza Facility inspection, the FDA observed a complete failure to inspect raw materials and inadequate microbial contamination controls. Ex. L at 2-3.

96. Following the Juno Facility inspection, Bristol-Myers, a gigantic pharmaceutical company that regularly files BLAs and New Drug Applications, could have no reasonable doubt concerning what systems the FDA would be scrutinizing. Bristol-Myers could have—and should have—ensured that Lonza corrected these issues before the Lonza Facility inspection, but it chose not to.

97. The other issues the FDA observed at the Lonza Facility, while different from those at the Juno Facility, reflected the opposite of Diligent Efforts. For example:

- a. The FDA observed that materials intended for use within the United States were stored in the same bin within the same freezer that stored not only materials intended for foreign markets with different manufacturing requirements—but also materials that had been rejected by quality control. *Id.* at 1.
- b. Freezer bins containing materials were “poorly maintained and organized.” For example, the FDA noted “the bottom of the freezer was filled” with “overturned” bottles and “substantial frost” had built up on bottles. *Id.*
- c. Materials were labeled in a manner that made mix-ups likely. For example, “[b]ottles of both accepted and rejected material [we]re designated by a ‘RELEASED’ label that has green background and black text with identical font.” Thus, material that had failed quality control easily could have been confused for material that had passed. *Id.*
- d. The FDA also observed conduct in direct contravention of express written procedures, including procedures that required freezers containing quarantined materials to be kept locked and that required expired batches of drug materials to be discarded. Batches that had expired on April 30, 2020—more than seven months earlier—were still at the facility at the time of the FDA’s inspection. *Id.* at 2.

98. Bristol-Myers first responded to the Form 483 for the Lonza Facility on December 18, 2020, the same day it submitted its supplemental response to the Juno Facility Form 483. This response, like the first response to the Juno Facility Form 483, was deficient and required Bristol-Myers to submit additional information, which it did on December 23, 2020, just days before the Liso-cel Milestone and in the middle of the winter holidays.

99. Had Bristol-Myers used Diligent Efforts, the myriad violations identified by the FDA at the Juno Facility and Lonza Facility—and the delay that resulted—would not have happened and the Liso-cel Milestone would have been achieved.

#### **IV. Bristol-Myers Refused To Reveal Any Information Concerning Its Efforts To Meet The Milestones Despite Its Contractual Obligation To Do So**

100. When these developments became public knowledge, certain CVR holders became concerned that Bristol-Myers had not complied with the CVR Agreement. They directed the Trustee, acting on their behalf under the CVR Agreement, to investigate Bristol-Myers’s compliance with the CVR Agreement and, if appropriate, to take action to enforce their rights.



101. To that end, the Trustee sent Bristol-Myers a letter on December 29, 2020 notifying Bristol-Myers that the Trustee was exercising its contractual right to inspect Bristol-Myers's books and records. Ex. A. § 4.2(f). Specifically, the Trustee requested:

- a. All documents consisting or concerning communications with the FDA concerning the amendment which resulted in the FDA extending the PDUFA date for Liso-cel, including any communications prior to May 13, 2020 concerning any manufacturing or other issues in any FDA communication relating to such extension;
- b. All documents constituting or concerning communications with the FDA concerning inspection of any facility identified in the BLA as a manufacturing site for Liso-cel;
- c. All documents addressing the risk of delay for approval of the Liso-cel BLA generated by Bristol-Myers or Celgene Corporation either before or after the CVR Agreement execution date;
- d. Documents sufficient to show all contingency planning for the manufacture of Liso-cel to avoid any risk of delay or failure of a Pre-License Inspection;
- e. All documents constituting or concerning any analysis done in the last 120 days concerning the impact on the financial statements or prospects of Bristol-Myers in the event the Liso-cel Milestone was not achieved;
- f. All documents constituting or concerning efforts by Bristol-Myers to educate relevant employees as to Bristol-Myers's obligations to use Diligent Efforts to achieve the Liso-cel Milestone.

102. Providing the information requested should have been easy for Bristol-Myers. As noted above, the CVR Agreement specifically requires Bristol-Myers to “use commercially reasonable efforts to keep, and [to] cause its Subsidiaries to use commercially reasonable efforts to keep, true, complete and accurate records in reasonably sufficient detail to enable the [CVR] Holders to determine if [Bristol-Myers] has complied with its obligations under th[e] CVR Agreement.” *Id.* § 7.5.

103. Bristol-Myers refused to provide any information, asserting that its obligation to keep and deliver records was instantly extinguished upon the failure to achieve the Liso-cel Milestone—an interpretation of the CVR Agreement that this Court ultimately rejected.

**V. Bristol-Myers Failed To Use Diligent Efforts To Achieve The Milestones, Causing It To Miss The Liso-cel Milestone Approval Date By Just Thirty-Six Days**

104. Following the three-month delay caused by Bristol-Myers's filing of a major amendment to the Liso-cel BLA, the two calamitous facility inspections resulting in Forms 483 identifying violations, and the inadequate responses to those Forms 483, the Liso-cel Milestone passed on December 31, 2020 without FDA approval.

105. Thirty-six days later, the FDA approved the Liso-cel BLA. Had Bristol-Myers used Diligent Efforts to achieve the Liso-cel Milestone—efforts which would have avoided a major amendment that caused at least a three-month delay and two Forms 483 that caused several more months of delay—Bristol-Myers would have met the deadline.

106. Had Bristol-Myers used Diligent Efforts to reach the Liso-cel Milestone, Bristol-Myers would be obligated to pay \$6.7 billion to CVR holders under the CVR Agreement.

107. Bristol-Myers did not use Diligent Efforts. That much is evident by examining the FDA approval process for Gilead's therapies Yescarta and Tecartus and Novartis's therapy Kymriah. These three therapies, each designated as a Breakthrough Therapy, are CAR-T Therapies that use a similar process as Liso-cel to treat lymphoma. Each therapy has equivalent or lower projected revenue, is less efficacious, has a higher likelihood of side effects, and is priced lower than Liso-cel. As Bristol-Myers has explained, it is Liso-cel that is "best-in-class"—not Yescarta, Kymriah, or Tecartus. Thus, Bristol-Myers had even more incentive to obtain FDA approval for Liso-cel quickly so that Liso-cel could be marketed and sold.

108. Nevertheless, Yescarta, Kymriah, and Tecartus moved through the FDA approval process with substantially more ease. Neither Gilead nor Novartis submitted a major amendment to any BLA. Overall, each submitted 40% to 80% fewer amendments to the respective BLAs than Bristol-Myers submitted for Liso-cel. And although Yescarta and Kymriah received Forms 483,

no responses were reported as containing “unclear and questionable points,” nor are there any reports that the FDA requested additional responses to the Yescarta or Kymriah Forms 483 because initial responses were deficient.

109. Ultimately, Yescarta, Kymriah, and Tecartus were approved in a substantially shorter periods than Liso-cel:

Therapy	BLA Submission Date	FDA Approval Date	Days from Submission to Approval
<b>Yescarta</b>	March 31, 2017	October 19, 2017	202 Days
<b>Kymriah</b>	March 28, 2017	August 30, 2017	155 Days
<b>Tecartus</b>	December 11, 2019	July 24, 2020	226 Days
<b>Liso-cel</b>	December 19, 2019	February 5, 2021	415 Days

110. Had Bristol-Myers used Diligent Efforts to achieve the Liso-cel Milestone—as it was contractually obligated to do—the Liso-cel Milestone would have been met.

#### **VI. Bristol-Myers Tries To Thwart The CVR Holders’ Rights By Delisting The CVRs From The New York Stock Exchange And Instructing The DTC To Delete Its Position**

111. In stark contrast to the delay Bristol-Myers exhibited throughout the Liso-cel approval process, after the December 31, 2020 Milestone passed, Bristol-Myers wasted no time in attempting to wipe its \$6.7 billion liability to the CVR holders.

112. On New Year’s Day, January 1, 2021, knowing full well that UMB was investigating the sufficiency of its efforts under the CVR Agreement, Bristol-Myers issued a press release stating that “the Contingent Value Rights Agreement ... terminated automatically in accordance with its terms and the CVRs are no longer eligible for payment under the CVR Agreement.” Ex. B at 1.

113. On January 1, 2021, Bristol-Myers also moved immediately to instruct the NYSE to delist the CVRs on the false basis that the CVRs had been “extinguished.” *See* Ex. C at 2.

114. On January 6, 2021, UMB sent a letter to the NYSE objecting to the delisting. Bristol-Myers responded just one day later, falsely telling the NYSE that “all rights pertaining to the CVRs were extinguished by the automatic termination of the CVR Agreement in accordance with its terms,” *id.*, even though the CVR Agreement explicitly states that the provisions allowing the Trustee to bring suit for breaches survive termination and that termination “*shall not relieve* any Party of *any liability* arising from any material breach of its obligations.” Ex. A § 1.16 (emphases added). When UMB raised this point in response to Bristol-Myers’s letter, Bristol-Myers doubled down, insisting that the CVRs must be delisted because all rights related to the CVRs had been “extinguished” and the CVRs “no longer exist.”

115. As of that time, 99% of the CVRs were registered in the name of Cede & Co., the nominee of the DTC, which is the custodian for all CVR holders who held registered securities. The DTC is a custodian and depository that exists for the purpose of facilitating electronic trading among its participant banks. The DTC and Cede & Co. make no economic decisions and take no shareholder actions themselves. CVR holders can ask the DTC for proxies in order to act as a Holder.

116. After delisting the CVRs from the NYSE, the Corporate Secretary of Bristol-Myers wrote to the DTC on January 11, 2021, directing it to “delete the entire position” for the CVRs. Ex. M. Bristol-Myers stated falsely that the CVRs were “null, void and worthless” and agreed to indemnify the DTC and Cede & Co. *Id.* Bristol-Myers was aware that litigation over the CVRs was imminent and that the CVRs continued to trade at positive values in anticipation of a recovery

from the Trustee's investigation or litigation. Bristol-Myers directed the DTC to delete the CVRs from its position just 24 days after it received the Instrument appointing UMB as Trustee.

117. On January 19, 2021, UMB contacted the DTC, asking whether the DTC required any action by UMB to keep the CVRs in its system. Ex. N. Later that same day, the DTC removed the CVR positions from its systems.

118. UMB has repeatedly attempted to cause the DTC to revive the CVRs on its system. On May 12, 2021, the DTC asked UMB for "any information" UMB could provide "regarding the [] CVR," because the CVR "holders [were] stating that [the CVRs] should be reinstated." Ex. O. UMB responded: "We agree that the CVRs remain outstanding and should be reinstated as a live position .... The company has taken the position that the CVRs are worthless due to the failure to achieve the milestones. UMB, as trustee, believes the company has reached that conclusion prematurely." *Id.* UMB stated that it had "retained counsel and [was] investigating" and "believe[d] it is quite possible that there will ultimately be a distribution on the CVRs." *Id.* UMB further explained that CVRs were still being traded via paper trades "at prices north of \$1/share," so "[o]bviously, there remains a strong desire by holders of the CVRs to be allowed to trade more conventionally." *Id.*

119. On June 21, 2021, UMB again wrote to the DTC, copying counsel for Bristol-Myers, requesting "that DTC reinstate the CUSIP for the CVRs, or, in the alternative, establish and maintain an escrow CUSIP to facilitate any future distributions to Holders of CVRs." Ex. P. UMB explained that "[t]he CVRs remain outstanding and there continues to be an active market for the CVRs." *Id.* at 3.

120. On July 6, 2021, UMB again wrote to the DTC, stating that it had not received a response to its letter seeking reinstatement of the CVR position. *Id.* UMB made clear that "[t]his

is a pressing matter and [it] would welcome the opportunity to discuss it ... at [the DTC's] earliest convenience.” *Id.* On July 13, 2021, the DTC responded to UMB, stating that it “cannot take any action in response to [UMB's] request, unless so instructed by [Bristol-Myers] or its agent.” Ex. Q at 5. It therefore “recommend[ed] that [UMB] direct [its] queries and requests to the issuer,” Bristol-Myers. *Id.* Bristol-Myers did not respond to UMB's or the DTC's letters, effectively refusing to undo its direction to the DTC, because its position was that all rights associated with the CVRs had been extinguished and that the CVRs were therefore valueless.

121. This Court's June 24, 2022 decision addressing Bristol-Myers's first motion to dismiss dismantled Bristol-Myers's position. *UMB Bank, N.A.*, 2022 WL 2290609, at \*2-3. Bristol-Myers argued that the Trustee's ability to notice an Event of Default and enforce the Agreement “terminated” on January 1, 2021. In denying Bristol-Myers's motion, the Court noted that that “the CVR Agreement explicitly provides that Article 8, which empowers [the Trustee] to bring suit, ‘shall survive termination of this CVR Agreement’ and that ‘the termination of this CVR Agreement shall not relieve any Party of any liability arising from any material breach of its obligations under this CVR Agreement occurring prior to the Termination Date.’” *Id.* Despite this ruling, Bristol-Myers has taken no steps to rectify its inaccurate assertions to the NYSE and the DTC.

122. To this day, Bristol-Myers informs CVR holders that “[b]ecause the milestone of approval of [L]iso-cel by December 31, 2020 was not met, the CVR agreement has automatically terminated in accordance with its terms ... and the CVRs are no longer eligible for payment.” Acquisition FAQs for Celgene shareholders, Bristol Myers Squibb, <https://www.bms.com/investors/shareholder-services/shareholder-faq.html> (last visited Feb. 3, 2025).

123. At oral argument on its second motion to dismiss, Bristol-Myers’s counsel acknowledged that, because of Bristol-Myers’s direction to the DTC to remove the CVRs from its system, the CVR Agreement’s provisions governing CVR holders’ rights, and in particular, the right to appoint a Trustee to pursue litigation, have been subverted: “[Section 4.10, which governs appointment of a Trustee] is not expressly carved out of the termination ..., but Article VIII [Remedies of the Trustee and Holders on Event of Default] is, and there’s no way to apply Article VIII without going through Section 4.10 if Equiniti were to resign.... There are other provisions where majority holders can get involved in [appointing a Trustee] ... *but it would be difficult [to appoint a new Trustee] because the CVRs were delisted, the CVRs don’t exist anymore, the security register, to my knowledge, is the same as it was on December 31st, which is the one that is before the Court, and I don’t know that DTC has records for the period after that because it removed the CUSIP permits from its system. That would be hard ....*” Ex. J at 72:20-73:18 (emphasis added). Bristol-Myers, in its motion to dismiss UMB’s Complaint, now takes the opposite position, arguing that “[v]oting rights that previously accompanied the CVRs expired with the securities.”

124. After the Court dismissed the prior action against UMB for lack of standing, on the ground that the CVR holders were required to obtain DTC authorization to act, certain CVR holders asked the DTC to revive the CVRs on its system to enable them to seek DTC authority for any present day actions under the CVR Agreement. If the DTC revives the CVRs in its system, the same banks and custodians who held CVR shares in January 2021 would remain beneficial holders today. No securities held through the DTC have electronically traded since that date.<sup>8</sup> While the

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<sup>8</sup> Economic interests in those securities may have changed hands through participations or assignments of interest, but those transactions do not impact which entities are holders of the CVRs.

DTC has stated that it has the practical ability to reinstate the CVRs to the position they were in as of January 2021, it will not do so without direction from Bristol-Myers.

125. In January 2021, Bristol-Myers breached the plain language of the CVR Agreement. Section 3.5(a) of the CVR Agreement states that “[Bristol-Myers] shall cause to be kept at the office of the Trustee a register (... the “Security Register”) in which ... *[Bristol-Myers] shall provide for the registration of [the CVRs] and of transfers of [the CVRs].*” Ex. A (emphasis added). Section 1.4(c) provides that “ownership of [the CVRs] shall be proved by the Security Register.” Since January 2021, Bristol-Myers has also breached the covenant of good faith and fair dealing by attempting to make it impossible to satisfy any provision under the CVR Agreement that requires authorization from the DTC.

## **VII. The Trustee Sends Bristol-Myers A Notice Of Default, And Bristol-Myers Refuses To Cure Its Default**

126. An Event of Default exists under the CVR Agreement.

127. On March 4, 2021, UMB notified Bristol-Myers that Bristol-Myers was in Default under the CVR Agreement because, among other things, Bristol-Myers had breached its obligations to use Diligent Efforts to achieve the Liso-cel Milestone and had delisted the CVRs with the NYSE.

128. Bristol-Myers thus had actual notice of a claim for breaches of the CVR Agreement and an Event of Default no later than March 4, 2021. That breach and Event of Default has continued to date. Bristol-Myers’s breaches thus ripened into an Event of Default under the CVR Agreement on June 3, 2021.

129. On October 21, 2024, UMB sent Bristol-Myers a Notice of Continuing Default under the CVR Agreement because it still had not cured its ongoing Event of Default. That notice incorporated UMB’s prior notice issued on March 4, 2021.



130. Bristol-Myers continues to not pay CVR holders following its breach of its obligations to use Diligent Efforts to achieve the Liso-cel Milestone. Thus, even if no prior Event of Default existed, Bristol-Myers's breaches ripened into an Event of Default on January 19, 2025—ninety days after UMB's Notice of Continuing Default.

**COUNT I**

**Declaratory Judgment Under 28 U.S.C. § 2201 Against Bristol-Myers and Equiniti**

131. UMB incorporates the preceding paragraphs as if fully set forth herein.

132. In light of the Court's holding that Equiniti was not replaced by UMB in December 2020, an actual and justiciable controversy exists as to the identity of the Trustee.

133. UMB requests a declaratory judgment that (1) UMB is the Trustee under the CVR Agreement; and (2) Equiniti is no longer the Trustee under the CVR Agreement.

**COUNT II**

**Breach of Contract Against Bristol-Myers for Failure to Use Diligent Efforts Under the CVR Agreement**

134. UMB incorporates the preceding paragraphs as if fully set forth herein.

135. Section 7.8 of the CVR Agreement, which is incorporated by reference in each CVR, requires Bristol-Myers to use Diligent Efforts to achieve the Milestones set forth in the CVR Agreement.

136. Bristol-Myers failed to use Diligent Efforts to achieve the Liso-cel Milestone by, among other things, submitting an inadequate Liso-cel BLA to the FDA, causing a major amendment to the Liso-cel BLA (which, in turn, triggered a three-month extension to the Liso-cel PDUFA date), failing to maintain the Juno Facility and Lonza Facility adequately, failing to prepare those facilities for inspection by the FDA, and inadequately responding to at least some of the FDA's findings.

137. Each of these demonstrates Bristol-Myers's failure to exercise Diligent Efforts in violation of Section 7.8 of the CVR Agreement.

138. As a result of Bristol-Myers's breach of its obligation to use Diligent Efforts to achieve the Milestones, the FDA did not approve the Liso-cel BLA by December 31, 2020.

139. UMB notified Bristol-Myers of Bristol-Myers's breach on March 4, 2021, and again on October 24, 2024.

140. Bristol-Myers's breach has continued for ninety days since either of UMB's notices and continues to this date.

141. Bristol-Myers's breach of Section 7.8 of the CVR Agreement has ripened into an Event of Default pursuant to Section 8.1(b) of the CVR Agreement.

142. As a result, the beneficiaries of the CVRs, whom the Trustee represents in this action as trustee of an express trust, have suffered damages in an amount to be determined at trial.

### **COUNT III**

#### **Breach of Contract Against Bristol-Myers for Failure to Maintain a Security Register**

143. UMB incorporates the preceding paragraphs as if fully set forth herein.

144. Bristol-Myers has an ongoing obligation under CVR Agreement Section 3.5(a) to cause a Security Register to exist and to provide for the registration of ownership and transfer of CVRs therein. Like Section 4.10, Section 3.5 must be read to survive the Milestone date because it is necessary for the enforcement provisions of Article 8, which expressly survive termination.

145. Bristol-Myers directed the DTC to delete its participant electronic trading system for the CVRs on January 11, 2021. Bristol-Myers has also asserted that the Security Register is frozen as of December 31, 2020. Bristol-Myers has thus breached Section 3.5 of the CVR Agreement.

146. An Event of Default exists under the CVR Agreement.

147. Under Section 8.4 of the CVR Agreement, the Trustee has the right to assert claims “to protect and enforce its rights and the rights of the Holders under the CVR Agreement.”

148. Monetary damages cannot properly remedy the damages from Bristol-Myers’s breach of Section 3.5(a) because it affects and will continue to affect the rights of CVR holders and Holders and the Trustee.

149. Accordingly, UMB requests the Court (i) order specific performance of Bristol-Myers’s Section 3.5(a) obligation to cause a functional Security Register to be maintained, at its cost, and direct Bristol-Myers to direct the DTC to reinstate the CVRs and (ii) excuse performance of any provision of the CVR Agreement that requires utilization of the Security Register, and any requirement or prerequisite to obtain authorization from the Registered Holder, until such Security Register is established and the DTC has reinstated the CVRs.

**COUNT IV**  
**(In the Alternative)**

**Breach of the Implied Covenant of Good Faith and Fair Dealing Against Bristol-Myers**

150. UMB incorporates the preceding paragraphs as if fully set forth herein.

151. The CVR Agreement imposed on Bristol-Myers a duty of good faith and fair dealing, which included a duty not to frustrate CVR holders’ rights to enforce the CVR Agreement.

152. By delisting the CVRs from the NYSE and directing the DTC to delete its participant electronic trading system, Bristol-Myers frustrated the ability of individual CVR holders to obtain proxies from the DTC.

153. Bristol-Myers’s actions were taken in bad faith to thwart the CVR holders’ rights in the face of imminent litigation and breached the duty of good faith and fair dealing.

154. An Event of Default exists under the CVR Agreement.

155. Under Section 8.4 of the CVR Agreement, the Trustee has the right to assert claims “to protect and enforce its rights and the rights of the Holders under the CVR Agreement.”

156. Monetary damages cannot properly remedy the damages from Bristol-Myers's breach of the implied covenant because it affects and will continue to affect the rights of CVR holders and Holders and the Trustee.

157. Accordingly, UMB requests the Court (i) order Bristol-Myers to direct the DTC to reinstate the CVRs and (ii) excuse performance of any provision of the CVR Agreement that requires utilization of the Security Register, and any requirement or prerequisite to obtain authorization from the Registered Holder, until such Security Register is established and the DTC has reinstated the CVRs.

**COUNT V**  
**(In the Alternative)**  
**Declaratory Judgment Under 28 U.S.C. § 2201 Against Bristol-Myers**

158. UMB incorporates the preceding paragraphs as if fully set forth herein.

159. The Court has ruled that the CVR Agreement establishes as a condition precedent to action by a CVR beneficial holder that the beneficial holder first obtain a proxy from the Registered Holder of the beneficial holder's CVRs.

160. The Registered Holder for 99% of the CVRs was the DTC through its nominee Cede & Co.

161. By causing the DTC to delete its participant electronic trading system, Bristol-Myers thwarted and frustrated the ability of CVR beneficial holders to satisfy this condition precedent after January 2021.

162. Under Section 8.4 of the CVR Agreement, the Trustee has the right to assert claims "to protect and enforce its rights and the rights of the Holders under the CVR Agreement."

163. An actual and justiciable controversy exists as to whether beneficial holders must obtain a proxy from the Registered Holder of the beneficial holder's CVRs before exercising rights

under the CVR Agreement given Bristol-Myers's actions to thwart satisfaction of this condition precedent.

164. UMB therefore requests a declaratory judgment that any condition precedent of the CVR Agreement that would require a beneficial holder to obtain a proxy from the Registered Holder to act under the CVR Agreement is excused.

### **PRAYER FOR RELIEF**

**WHEREFORE**, UMB respectfully requests that the Court grant the following relief:

- a. A declaratory judgment pursuant to 28 U.S.C. § 2201 that UMB is the Trustee and Equiniti is no longer the Trustee; and
- b. An order (i) requiring specific performance of Bristol-Myers's Section 3.5(a) obligation to cause a functional Security Register to be maintained, at its cost, directing Bristol-Myers to direct the DTC to reinstate the CVRs, and (ii) excusing performance of any provision of the CVR Agreement that requires utilization of the Security Register, and any requirement or prerequisite to obtain authorization from the Registered Holder, until such Security Register is established; or, in the alternative,
- c. A declaratory judgment pursuant to 28 U.S.C. § 2201 that any condition precedent of the CVR Agreement that requires a beneficial holder to obtain a proxy from the Registered Holder, is excused; and
- d. An award of monetary damages in an amount to be proven at trial on Count II;
- e. An award of pre- and post-judgment interest (including pursuant to the CVR Agreement);
- f. An award of reasonable attorney's fees and costs of suit; and
- g. An award of any and all other such relief, legal or equitable, as the Court may deem just and proper under the circumstances.

**JURY DEMAND**

Plaintiff demands a trial by jury for all issues so triable as a matter of right.

Dated: February 3, 2025

Respectfully submitted,

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